CURRICULUM DEVELOPMENT AWARD IN INTERDISCIPLINARY RESEARCH

RELEASE DATE: October 29, 2003

RFA Number: RFA-GM-04-003

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:
National Institutes of Health (NIH)
(http://www.nih.gov)

THIS RFA IS DEVELOPED AS AN NIH ROADMAP INITIATIVE (http://nihroadmap.nih.gov/). **ALL NIH INSTITUTES AND CENTERS PARTICIPATE IN ROADMAP INITIATIVES. THE RFA WILL BE ADMINISTERED BY THE NIGMS ON BEHALF OF THE NIH**.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.859

LETTER OF INTENT RECEIPT DATE: January 27, 2004
APPLICATION RECEIPT DATE: February 24, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The Curriculum Development Award in Interdisciplinary Research supports the development of innovative courses, curricula and educational approaches designed to train interdisciplinary scientists in emerging areas of biomedical, behavioral and quantitative sciences. These programs are focused on preparing undergraduate, predoctoral, or postdoctoral candidates, or combinations of these, to conduct research in team settings that are highly interdisciplinary and collaborative and to train future leaders who can catalyze the integration of multiple disciplines. The courses and curricula may be organized around an interdisciplinary research theme which will form a framework for integrating education and training across disciplines. To achieve the breadth and diversity of courses and curricula needed to meet these goals, applicants must include multiple departments and may also include multiple centers, schools or institutions. This award is intended to a) support the development of new didactic programs in interdisciplinary research training at institutions that do not currently offer them, or b) support the improvement or expansion of curricula at institutions with existing programs. As part of this program, awardees will be expected to develop and implement the courses or curricula in their institution(s). It is expected that such courses and curricula will be models that could be transferable to other institutions in whole or in part. Applicants interested in applying for interdisciplinary research training support through other mechanisms should refer to the related roadmap initiatives on interdisciplinary training at http://nihroadmap.nih.gov/interdisciplinary/grants.asp.

TRAINING OBJECTIVES

Background and Description

The National Institutes of Health (NIH) is engaged in a series of activities collectively known as the "NIH Roadmap," whose goal is to accelerate both the pace of discovery in the life sciences and the translation of therapies from bench to bedside. In the course of developing the NIH Roadmap, it has become increasingly clear that scientific advances are being made at the interfaces of traditional disciplines, and approaches to science are becoming more integrative. This requires a cooperative effort, typically in the form of investigators from diverse research backgrounds working collectively across traditional disciplinary boundaries to answer scientific questions and achieve specific endpoints. This also requires a workforce capable of crossing disciplinary boundaries and leading and participating in integrative and team approaches to complex biomedical problems. Building research teams for the future has therefore emerged as one of the major themes in Roadmap implementation. Additional information about the NIH Roadmap can be found on the NIH website at http://nihroadmap.nih.gov/.

Biomedical research encompasses a large number of scientific disciplines in addition to the biological sciences, including but not limited to the behavioral, quantitative, engineering and computer sciences. Distinct disciplinary perspectives represent significant sources of strength to the overall research enterprise because each

discipline has its own intellectual history, experimental and analytic approaches, and theoretical context that produce a unique way of thinking about a problem. Nevertheless, as scientific capabilities move forward, increasingly complex questions arise, and these often require the convergence of perspectives from multiple disciplines. Over the years, the Institutes and Centers (ICs) at NIH have developed many initiatives, mechanisms and programs to support multidisciplinary research-that is, research that brings together researchers from different disciplines to focus on a circumscribed problem.

It is becoming apparent that, in some cases, the collaborative nature of disciplines that characterizes multidisciplinary research is not sufficiently sustained to address, in a comprehensive way, challenging problems in biomedical and behavioral research. Rather, interdisciplinary research, which integrates several disciplinary approaches in a more sustained and systematic fashion, may be required to tackle these more complex problems. Integrating different disciplines in this way holds the promise of opening up currently unimagined scientific avenues of inquiry, and in the process, may form whole new disciplines. Historical examples of this include the development of genomics, which was formed from genetics, molecular biology, analytical chemistry, and informatics. Neuroscience is another example in which multiple disciplines have, in a less directed way, blended and evolved into a new discipline. Thirty years ago, students of the brain might have identified themselves as anatomists, physiologists, or psychobiologists, but today they would consider themselves neuroscientists.

Combining particular aspects of different disciplines to develop entirely new ways to approach biomedical and behavioral research problems is daunting in many ways. NIH recognizes the value and enormous contributions that existing interdisciplinary approaches have made and are making to biomedical research. However, the Roadmap is focused on stimulating the development of new and innovative interdisciplinary approaches and training. NIH is proposing a series of initiatives that aim to provide investigators with the training to effectively lead and engage in integrative and team approaches to complex biomedical problems. Collectively, the initiatives provide opportunities for integration of disciplines at all stages of investigators' careers, facilitate communication among the disciplines, and ensure the development of necessary infrastructure to build the workforce for the research teams for the future. Additional information on initiatives associated with building research teams of the future can be found on the NIH website at http://nihroadmap.nih.gov/interdisciplinary/index.asp.

The Interdisciplinary Curriculum Development Awards are expected to support the development of innovative courses and curricula designed to train interdisciplinary scientists in emerging areas of biomedical and behavioral science. These curricula can be designed for undergraduate, predoctoral or postdoctoral students, or combinations of these. The NIH is particularly interested in programs that encourage the integration of quantitative, physical, behavioral, or social sciences with the traditional biomedical sciences that will lead to the creation of a new interdisciplinary research area.

MECHANISM OF SUPPORT

This RFA will use the NIH K07 mechanism, using the Leadership provision of this award to support curriculum development (see http://grants.nih.gov/grants/guide/pa-files/PA-00-070.html). Planning, direction, and execution of the program will be the responsibility of the principal investigator. However, the institution must demonstrate a commitment to the purposes of this award for course or curriculum development in the specified area. The project period is for up to five years. Competing renewals to continue the development of courses/curricula developed under this award will not be considered. At this time, plans for reissuing the RFA are indefinite. The anticipated award date is 09/30/2004. In most cases, these awards will be made to develop new educational approaches for which the institution will subsequently assume support. This RFA uses just-in-time concepts.

FUNDS AVAILABLE

The participating ICs intend to commit approximately $1.5 million in FY04 to fund approximately 5-10 new grants in response to this RFA. An applicant may request a project period of up to five years. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the ICs provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. The Institution may contribute resources in terms of released time for the Principal Investigator and support for clerical and administrative personnel, travel, consultants and meetings, faculty support, core facilities and space and equipment.

ELIGIBLE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government
o Domestic institutions/organizations
o Foreign institutions are not eligible to apply.

An institution may submit more than one application if it proposes the development of distinctly different interdisciplinary curricula/courses. Proposed educational experiences must be distinct from those training programs currently receiving NIH support or other federally funded support. There must be a commitment from the nominating institution that the course(s) or curricula will become an integral part of the academic offerings of the institution.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed curriculum development is invited to work with their institution to develop an application for support. The Principal Investigator should possess the research and training expertise, and leadership and administrative capabilities required to develop and implement an interdisciplinary course/curriculum of this scope. The PI must be willing to spend between 25-50% of his/her full-time professional effort on course(s) and curriculum development for the period of the award, and must identify appropriate collaborator(s) from the relevant disciplines who will agree to collaborate on the development of the course(s) and curricula. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs. Principal Investigators must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Card or some other verification of legal admission as a permanent resident.

All potential applicants are strongly encouraged to contact the NIH staff listed below to discuss their eligibility and the specific provisions of this award.

SPECIAL REQUIREMENTS

Program: The Principal Investigator is expected to develop courses or curricula at the undergraduate, graduate or postdoctoral level (or combinations of these) that integrate the principles and conceptual approaches of multiple, diverse disciplines in emerging areas of biomedical research, including but not limited to the behavioral, quantitative, engineering and/or computer sciences. The curricula may be organized around an interdisciplinary theme that provides a framework for merging concepts and approaches from multiple disciplines into an integrated course/curriculum. These efforts should also encourage collaboration and interaction across departments, schools and/or institutions.

Environment: The institution must have strong training program(s) in the individual disciplines which are being integrated through the interdisciplinary course(s) or curricula that are being developed. The institution must demonstrate a commitment to the further development and implementation of these courses and curricula following the award. The institution must provide assurance that the Principal Investigator is an integral part of its research and academic programs.

Allowable costs:

Salary: This award will provide salary and fringe benefits for the recipient for levels of effort between 25 and 50 percent. The total salary requested must be based on the Principal Investigator's full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. The salary will always be pro-rated

for the percentage of time/effort of a full-time position, based on the institutional salary scales, keeping the DHHS salary cap as a maximum for which the amount is determined.

The institution may supplement this award contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived.
In no case may DHHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the Curriculum Development Award.

Research Support: A maximum of $50,000 per year may be requested for ancillary needs, such as collaborators, consultants, equipment, computer time, etc. All requests for ancillary support must be justified. In no case will the allowance provided exceed $50,000. Salaries for mentors or for secretarial, technical and/or administrative assistance are not allowed.

Facilities and Administrative (F&A) Costs: F&A costs will be reimbursed at 8 percent of modified total direct costs, or at the actual indirect cost rate, whichever is less.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Alison E. Cole, Ph.D.
Division of Pharmacology, Physiology and Biological Chemistry
National Institute of General Medical Sciences
Building 45, Room 2AS-49K
Bethesda, MD 20892
Telephone: (301) 594-3349
FAX: (301) 480-2802
Email: colea@nigms.nih.gov

o Direct your questions about peer review issues to:

Helen R. Sunshine, Ph.D.
Office of Scientific Review
National Institute of General Medical Sciences, NIH
45 Center Drive, Room 3AN.12F, MSC 6200
Bethesda, MD 20892-6200
Telephone: (301) 594-2881
FAX: (301) 480-8506

Email: sunshinh@nigms.nih.gov

o Direct your questions about financial or grants management matters to:

Antoinette Holland
Grants Administration Branch
National Institute of General Medical Sciences
45 Center Drive, Room 2AN.50B, MSC 6200
Bethesda, MD 20892-6200
Telephone: (301) 594-5132
FAX: (301) 480-3423
Email: hollanda@nigms.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Alison E. Cole, Ph.D.
Division of Pharmacology, Physiology and Biological Chemistry
National Institute of General Medical Sciences
Building 45, Room 2AS-49K
Bethesda, MD 20892
Telephone: (301) 594-3349
FAX: (301) 480-2802
Email: colea@nigms.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by

calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo,
Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTARY INSTRUCTIONS

The application must address the following issues:

Principal Investigator:

Describe the Principal Investigator's commitment to developing and implementing an interdisciplinary course(s) or curricula, which meet the scientific and educational requirements of the interdisciplinary fields and the institution.

Provide evidence that the Principal Investigator has the capacity to develop and implement course(s) or curricula that are based on sound research concepts and educational principles.

Course or Curriculum Development Plan:

Describe the plan and how it fits into the institutional plans and goals. Explain how this curriculum is distinguished from other curricula within the existing educational infrastructure and framework of the applicant/participating institution(s). Describe the immediate and long-term objectives of the award and how those objectives will meet the needs for expansion or enhancement of the academic or research capacity of the institution in interdisciplinary research.

Environment and Institutional Commitment:

The institution must provide evidence of commitment and support for the proposed program. There must be evidence of support for the Principal Investigator and his/her course and/or curricula development and implementation plans and for the further enhancement of the interdisciplinary scientific area.

Collaborator's Statement:

Principal Investigators must include information about any collaborator(s) including her/his research and training qualifications. The application must also include

information describing the nature and extent of collaboration that will occur during the proposed award period.

Budget:

Budget requests must be provided according to the instructions in form PHS 398. The request for ancillary support, i.e., essential books, travel, consultants, equipment, computer time, etc., must be justified and specified by category.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center For Scientific Review
National Institutes Of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Helen R. Sunshine, Ph.D.
Office of Scientific Review
National Institute of General Medical Sciences, NIH
45 Center Drive, Room 3AN.12F, MSC 6200
Bethesda, MD 20892-6200

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the

applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIGMS. Incomplete or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIGMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
o Receive a written critique
o Receive a second level review by an appropriate National Advisory Council or Board.

It is strongly recommended that prospective applicants contact the staff person listed under INQUIRIES early in the planning phase of the application. Such contact will help ensure that applications are responsive to the overall intent of this award.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major impact and thus deserve a high priority score.

Principal Investigator:

o Evidence of the Principal Investigator's excellence in research and academic activities, and the quality and breadth of prior scientific training experience.

o Commitment to developing and implementing academic course(s) or curricula which meet the scientific and educational requirements of the interdisciplinary field and the institution.

o Evidence of the capacity to develop and implement course(s) or curricula that are based on sound research concepts and educational principles.

o Evidence of potential to become a leader in developing educational interdisciplinary scientific programs at the institution(s).

Course/Curricula Development Plan:

o Quality, feasibility and innovation of course or curricula development and implementation plans for interdisciplinary research training.

o Appropriateness of the plan to the goals of this program. Adequacy of the justification provided for the need for the proposed curriculum relative to other on-going education and/or training activities being sponsored within the institution(s).

o Immediate and long-term objectives of the award and how those objectives will meet the needs for expansion or enhancement of the academic or research capacity of the institution in the interdisciplinary research area.

o Quality of plan to disseminate the materials nationwide through such means as Web postings, presentations at meetings, workshops, etc.

Environment:

o Commitment of the institution to strengthening interdisciplinary research and education activities in areas of interest to the NIH. For example, an institutional commitment to create a new degree program, at either the undergraduate or graduate level, in the proposed interdisciplinary area, would be regarded as compelling evidence of institutional support.

o Merit of the institution's plan to strengthen their interdisciplinary training.

o Scope and nature of collaboration among participating schools and departments.

Collaborator(s):

o The collaborator's capabilities to contribute to the goals of the program.

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below.)

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below.)

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: January 27, 2004
Application Receipt Date: February 24, 2004
Peer Review Date: June-July 2004
Council Review: September 2004
Earliest Anticipated Start Date: September 30, 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review)
o Availability of funds
o Programmatic priorities

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

SHARING RESEARCH DATA: Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible.
http://grants.nih.gov/grants/policy/data_sharing
Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported

by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: (if applicable) NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov/.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any

portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health
and Human Services


National Institutes of Health (NIH)
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